DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20381/S-048
NDA 22078/S-015

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Richard Leber
Manager, Regulatory Affairs-PPG
1 N. Waukegan Road
Dept PA77/Building AP30
North Chicago, IL 60064

Dear Mr. Leber:

Please refer to your Supplemental New Drug Applications (sNDAs) dated March 16, 2012, received March 19, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Niaspan (niacin extended release), 500 mg, 750 mg, and 1000 mg and Simcor (niacin ER/simvastatin) Tablets, 500 mg/20 mg, 500 mg/40 mg, 750 mg/20 mg, 1000 mg/20 mg, and 1000 mg/40 mg.

We acknowledge receipt of your amendments dated September 13 and October 4, 2012 (Niaspan), and September 13 and November 19, 2012 (Simcor). We also acknowledge receipt of your email dated January 25, 2013, that includes the agreed-upon labeling for Niaspan, and the email dated February 21, 2013, that includes the agreed-upon labeling for Simcor.

These "Prior Approval" supplemental new drug applications provide for revisions to the package inserts (and patient package insert labeling for Niaspan) to include information from the clinical trial "Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes (AIM-HIGH)".

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being

Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Eric Colman, MD
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC C COLMAN
02/21/2013